Proposed Decision Memo for Lung Volume Reduction Surgery (CAG-00115R2)

Decision Summary

Through this decision memorandum, CMS proposes to modify CMS Publication 100-3 Section 240.1.A.2.c to state:

CMS has determined that LVRS performed on or after xx/xx/xx (18 months from the effective date of this decision)is reasonable and necessary only when performed at facilities that are certified by the Joint Commission on Accreditation of Healthcare Organizations Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the October 25, 2004 Disease Specific Care Certification Program packet) *or* when performed at facilities that are Medicare-approved for lung or heart-lung transplantation. Surgeries performed between January 1, 2004 and xx/xx/xx are reasonable and necessary when performed at facilities that were approved by the National Heart Lung and Blood Institute (NHLBI) to participate in the National Emphysema Treatment Trial (NETT), facilities that are Medicare approved for lung or heart-lung transplantation, or facilities that have been certified by the Joint Commission.

CMS proposes that lung or heart-lung transplant facilities have Medicare approved transplant status at the time the LVRS is performed. CMS proposes that facilities that seek to satisfy the facility requirement through Joint Commission certification be certified at the time the LVRS is performed. NETT facilities that are not Medicare approved for lung or heart-lung transplantation are encouraged to become Joint Commission-certified or a Medicare approved transplant center within 18 months after the effective date of this decision in order to continue to receive Medicare payment for LVRS after that date. A list of approved facilities will be continuously updated and available on the CMS web site at http://www.cms.hhs.gov/coverage/lvrsfacility.pdf.

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Proposed Decision Memo

TO: Administrative File: CAG 00115R2
Lung Volume Reduction Surgery

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SUBJECT: Proposed Coverage Decision Memorandum for Lung Volume Reduction Surgery

DATE: August 18, 2005

I. Proposed Decision

Through this decision memorandum, CMS proposes to modify CMS Publication 100-3 Section 240.1.A.2.c to state:

CMS has determined that LVRS performed on or after xx/xx/xx (18 months from the effective date of this decision) is reasonable and necessary only when performed at facilities that are certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the October 25, 2004 Disease Specific Care Certification Program packet) *or* when performed at facilities that are Medicare-approved for lung or heart-lung transplantation. Surgeries performed between January 1, 2004 and xx/xx/xx are reasonable and necessary when performed at facilities that were approved by the National Heart Lung and Blood Institute (NHLBI) to participate in the National Emphysema Treatment Trial (NETT), facilities that are Medicare approved for lung or heart- lung transplantation, or facilities that have been certified by the Joint Commission.

CMS proposes that lung or heart-lung transplant facilities have Medicare approved transplant status at the time the LVRS is performed. CMS proposes that facilities that seek to satisfy the facility requirement through Joint Commission certification be certified at the time the LVRS is performed. NETT facilities that are not Medicare approved for lung or heart-lung transplantation are encouraged to become Joint Commission-certified or a Medicare approved transplant center within 18 months after the effective date of this decision in order to continue to receive Medicare payment for LVRS after that date. A list of approved facilities will be continuously updated and available on the CMS web site at http://www.cms.hhs.gov/coverage/lvrsfacility.pdf.

Further, CMS proposes removing the following language from the national coverage determination (NCD) (Publication 100-3, Section 240.1.A.1):

"National Emphysema Treatment Trial (NETT) participants (effective for services performed on or after August 11, 1997):

Medicare provides coverage to those beneficiaries who are participating in the NETT trial for all services integral to the study and for which the Medicare statute does not prohibit coverage."

The NETT clinical trial has ended and therefore the language is no longer applicable.

II. Background

LVRS is a surgical procedure for patients that have severe emphysema where damaged lung tissue is selectively removed. Emphysema is a progressively disabling lung disease that mostly affects current or former cigarette smokers. Over two million Americans suffer from emphysema. LVRS has been shown to alleviate symptoms and improve health outcomes for patients with selected clinical characteristics when provided by experienced facilities.[1] As with any surgical procedure, there are risks and complications associated with LVRS. A detailed discussion of emphysema and the risks and benefits of LVRS is available in the August 20, 2003 decision memorandum at http://www.cms.hhs.gov/coverage/download/id96.pdf [PDF, 231KB].

On February 17, 2005 the Centers for Medicare and Medicaid Services (CMS) formally received a request submitted by the Joint Commission to allow hospitals certified through its disease- specific care certification program for LVRS to be Medicare-approved LVRS facilities. The agency then began the review of this request for reconsideration of the previous national coverage determination (NCD) for LVRS. The purpose of this reconsideration is to evaluate the LVRS program requirements developed by the Joint Commission in order to determine whether these criteria are consistent with the current Medicare requirements.

CMS is only reviewing the process for determining if LVRS facility standards are met. We are not reviewing any other standards in the LVRS NCD. All other requirements of the current Medicare NCD for LVRS remain applicable. Also, while this reconsideration proposes Joint Commission certification as an alternative mechanism to assess that facilities meet staff and facility requirements under Medicare, if requested by other third-party entities, CMS will evaluate additional programs designed to evaluate facilities wishing to furnish LVRS services.

III. History of Medicare Coverage

Prior to December 1995, Medicare did not have a national coverage policy regarding LVRS and coverage for the procedure was overseen by Medicare contractors. Due to concerns for patient safety and inadequate medical evidence supporting the procedure, CMS issued a national policy in December 1995 non-covering LVRS.

In 1996, CMS and the National Heart, Lung and Blood Institute (NHLBI) agreed to jointly sponsor the National Emphysema Treatment Trial (NETT), a multi-centered, controlled clinical trial to compare LVRS with medical management in the treatment of severe emphysema. Between 1996 and 2003 CMS only covered LVRS when it was performed on patients enrolled in the NETT.

The published results from the NETT served as the basis of the August 2003 Medicare decision memorandum mentioned above to broaden LVRS coverage in order to include provision outside of the trial for patients with particular clinical indications. In addition to carefully outlining the patient population, this decision allowed LVRS only to be performed in facilities that were Medicare-approved for lung transplants or had been approved as NETT centers. Expanded coverage for LVRS became effective on January 1, 2004.

IV. Timeline of Recent Activities

August 20, 2003	CMS issues the Decision Memorandum announcing the intention of CMS to cover LVRS for specific clinical indications and the intention to consider allowing a third party program to certify Medicare-approved LVRS facilities.

January 1, 2004	CMS coverage of LVRS becomes effective.
February 17, 2005	CMS opens a reconsideration for LVRS to review third party certification standards for facilities performing this procedure.
March 17, 2005	Initial 30-day public comment period closes.

V. FDA Status

LVRS is a surgical procedure that does not require FDA approval.

VI. Methods

In this memorandum, CMS compares the Joint Commission program requirements to the existing Medicare LVRS facility requirements that served as the basis for approving NETT centers and lung transplant centers in January 2004. Our examination consisted of:

- Reviewing the process used by the Joint Commission to develop their standards; and
- Comparing the Joint Commission standards with the general standards for LVRS facilities established by CMS and whether the LVRS-specific certification criteria proposed by the Joint Commission are at least equivalent to the CMS standards and therefore likely to identify facilities that furnish LVRS in a reasonable and necessary manner.

Further, CMS explains why the designation of currently approved NETT facilities will terminate in the future due to the cessation of oversight provided by NIH. We propose an alternative method for those hospitals to become certified so that they may continue to receive Medicare payment for covered LVRS procedures.

VII. Assessment

1. Assessment questions

In this assessment, CMS seeks to address the following questions:

- ***Are the Joint Commission standards at least equivalent to the CMS standards used to select NETT and transplant centers in the January 2004 decision?***

- ***Should facilities selected as NETT centers continue to be approved as LVRS facilities?***

- ***What impact will the proposed transplant regulation have on LVRS approved facilities[2]?***

2. Current CMS requirements for LVRS facilities

In the August 2003 decision memorandum, by selecting the sites that had been approved by NHLBI to participate in the NETT as Medicare-approved programs, CMS implicitly adopted the facility standards that had been utilized by NHLBI to identify facilities qualified to participate in the trial.[3] These requirements included, among others, that each facility had assembled an integrated team expert in pulmonary medicine, had a close working relationship with a lung or heart-lung transplantation center, and had the ability to provide relevant patient outcome data. CMS adopted the NHLBI-derived standards by initially restricting approved facilities to those that participated in the NETT in addition to Medicare-approved transplant centers, which were presumed to have met the above criteria. The NHLBI standards are explicitly stated below:

- The facility must ensure that all individuals who provide services and/or supervise services in the LVRS program are qualified to provide or supervise such services.

- The facility must identify a multidisciplinary LVRS team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training and experience in the relevant areas of pulmonary medicine, pulmonary rehabilitation, thoracic surgery, critical care anesthesia, and pulmonary radiological assessment.
- The primary surgeon participating in the program must have experience performing LVRS procedures.
- The pulmonary specialist(s) must have training and clinical expertise in managing and treating end-stage emphysema patients, have a firm understanding of pulmonary medicine and pulmonary rehabilitation, and have experience in managing patients undergoing LVRS.
- The facility must demonstrate a close working relationship with or be a Medicare lung or heart-lung transplantation center to ensure that patients are adequately evaluated for both LVRS and lung transplant prior to the surgical procedure.
- The facility must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, infectious disease control, pathology, radiology, physical therapy and blood banking as related to the provision of LVRS.
- The facility must establish and implement written policies to address and document adverse events that occur during the management of an LVRS patient.
- The facility must have a written informed consent process that informs each patient of: 1) the evaluation process; 2) the surgical procedure; 3) alternative treatments; 4) national and center-specific rates for potential surgical risks, hospital lengths of stays, 30-day mortality and other relevant outcome measures; 5) risk factors that could affect the success of the surgery; 6) the patient's right to refuse the intervention.

In addition, NHLBI required that NETT facilities had the capacity to collect, analyze and provide pre-operative, post-operative and follow-up data. Accordingly, the facility's quality improvement program would utilize objective measures to periodically evaluate the LVRS program's performance with regard to LVRS services and outcomes. Services and outcomes could include, but were not limited to patient selection criteria, consent practices, length of stay, surgical and medical complications and early (30-day) or late (90-day) mortality rates. LVRS programs maintain these and other relevant data (e.g., number of procedures performed by individual practitioners). In sum, we expected that each LVRS program would take actions resulting in performance improvements and would track performance to ensure that improvements were sustained.

In order to provide adequate access to LVRS while preserving a high standard of care, CMS also concluded that the NETT results were likely to be applicable to lung transplant centers for which CMS had already developed criteria for approval under the Medicare program. We believed that the kind of integrated team assembled at the NETT sites with expertise in pulmonary medicine – especially as it related to end-stage emphysema, pulmonary rehabilitation, thoracic surgery, critical care anesthesia, quality of life and dyspnea measurements, and pulmonary radiological assessment - would be present or could be readily established at Medicare-approved lung transplant facilities. We also understood that experienced lung and heart-lung transplant surgeons could perform LVRS with beneficial results given the overlap of skills required for both surgical procedures.

3. Joint Commission: Standard development

The proposal submitted to CMS for LVRS certification was developed within the framework common to all the disease-specific certification programs offered by the Joint Commission. It contains a core set of standards and the corresponding elements of performance for each standard applicable to the individual condition of interest, for example stroke or asthma. Elements of performance are measurable characteristics used to evaluate compliance with standards and thus inform the Joint Commission's review procedures. Elements of performance specifically required for certification of LVRS facilities were incorporated into this framework.[4]

In order to develop the LVRS-specific elements of performance in the proposed certification program, the Joint Commission assembled a task force composed of physicians representing the Society of Thoracic Surgeons, the American College of Chest Physicians, and other experts including cardiothoracic surgeons. These selected experts provided their view on the characteristics critical to the structure and operation of a program capable of providing appropriate services centered on this procedure as well as on patient inclusion/exclusion criteria.

To obtain public input, the Joint Commission posted the proposed LVRS requirements on its web site and solicited comments directly from over 60,000 individuals enrolled on the Joint Commission list serve. The comments received were incorporated where appropriate. The standards were reviewed again by the expert panel before a final LVRS certification program proposal was submitted to CMS.[5]

The proposed LVRS certification program involves a two-year award cycle with an off-site and an on-site evaluation in the first year and an off-site intra-cycle evaluation during the second year. Certification is limited to hospital-based programs. Review of pre- and post-surgery rehabilitation services is to be conducted as part of the evaluation of the hospital program's ability to provide or coordinate all required services. The proposed standards and elements of performance developed by the Joint Commission for LVRS certification and printed in the October 25, 2004 Disease Specific Care Certification Program packet are listed in appendix A.

4. External technology assessments

No external technology assessment was commissioned for this review.

5. MCAC

The Medicare Coverage Advisory Committee was not convened to review this issue.

6. Evidence-based guidelines

CMS is not aware of professional guidelines for LVRS.

7. Professional Society Position Statements

CMS is not aware of professional society statements regarding LVRS facility standards.

8. Initial Comment Period

During the initial 30-day public comment period, CMS received comments from 10 physician commenters with one on behalf of a professional society. Comments are available in their entirety at http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca_id=153.

Program Criteria

Multiple commenters supported the notion that NETT centers be automatically certified since these centers have already demonstrated their ability to perform LVRS. One supporter recommended that this be the case if one of the NETT surgeons remains at the facility. One commenter suggested that sensible restrictions should be in place and hospitals with a board certified thoracic surgeon (or equivalent), sufficient case volume, specialized units and available rehabilitation facilities should be able to perform LVRS.

Other commenters were concerned that credentialing would unnecessarily limit approved facilities. They commented that limiting facilities should not be an issue since this would limit patient access to LVRS and that LVRS does not generate scarce resource utilization concerns as transplants do. One commenter noted that currently approved facilities should be held to the same data reporting standards and re-certification requirements but should not need to undergo a new application with the Joint Commission. Rather than certification, one commenter recommended that a registry be used to compare facility outcomes with acceptable standards. An additional commenter recommended that the General Thoracic Database run by the Society of Thoracic Surgeons be an option for following LVRS programs and that this database is already in use by many centers. This same commenter supported third-party certification as delegated to the Joint Commission.

One commenter was concerned that this type of mandated disease-specific certification will become redundant as some assessments and tracking are already required by third-party accreditors (e.g. outpatient and inpatient care programs already reviewed by the Joint Commission).

Physician Criteria

Commenters stated that a board certified thoracic surgeon should be able to perform LVRS due to the lack of complexity of the procedure. One comment identified the Joint Commission's requirement for a minimum number of procedures as arbitrary. However, the same commenter did state that surgeons must be experienced and specialize in these types of cases and offered examples of other lung surgery experience that should deem a physician eligible to perform LVRS. Rather than physician competency, some commenters stated that patient selection and post-operative care management are primary drivers of patient outcomes. One commenter pointed out that the program certification criteria were inconsistent with the current Medicare requirements as the current criteria allow a transplant center with no LVRS experience to perform the procedure.

Coordination of Care

One commenter recommended that CMS eliminate the requirement that the surgical facility coordinate all pre-operative services which include rehabilitation and post-operative services. The commenter stated that these requirements place unnecessary burden on the facility-based provider and sever the relationship between the patient and their local providers.

One commenter stated agreement with the Joint Commission and CMS requirement that patients should obtain evaluations for both LVRS and transplant and that non-transplant facilities should arrange for patients to be objectively evaluated and educated on the risks of LVRS versus transplantation.

Although some commenters supported data collection, one commenter specifically pointed out that this type of reporting should be done only when possible and that follow-up testing would be inconvenient and expensive for the patient.

Clinical Indications

One commenter discussed the subjective nature of the inclusion and exclusion criteria stating that these criteria are impossible to audit and that such specific criteria run counter to relying on skilled practitioners to make determinations. This commenter recommended that patient outcomes be the basis of certification rather than specific clinical criteria.

One commenter pointed out that the high-risk patient population identified in the 2002 New England Journal article was not specifically excluded in the Joint Commission standards.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations made by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1862(l)(6)(A). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

We previously concluded that LVRS was reasonable and necessary for certain patients meeting specific criteria if performed in certain qualified facilities. We have been asked to modify this NCD to permit coverage in facilities that meet alternative standards. Except as noted below, all other aspects of the existing NCD remain unchanged.

Are the Joint Commission standards at least equivalent to the CMS standards used to select NETT and transplant centers in the January 2004 decision?

Usually, medical and surgical procedures can be performed successfully in most facilities that meet Medicare conditions of participation for hospitals. However, as indicated above, in the case of LVRS various other factors are related to the safety and effectiveness of the procedure. Coverage of this and other technically demanding procedures (such as lung transplantation) performed on severely ill patients requires more detailed criteria to identify the context in which they can be considered reasonable and necessary. In these instances, facilities and providers must have documented the competencies necessary to safely and effectively provide the technology or service in question.

Facility standards

As discussed earlier, by selecting the sites that had been approved by NHLBI to participate in the NETT as Medicare-approved programs, CMS implicitly adopted the facility standards that had been utilized by NHLBI to identify facilities qualified to participate in the trial. CMS did this by initially restricting approved facilities to those that participated in the NETT in addition to Medicare-approved lung and heart-lung transplant centers. We have listed those standards above.

The Joint Commission has established a disease-specific certification program for LVRS. The organization has requested through the NCD process that CMS approve its certification program. Although the Joint Commission standards include both patient selection and facility requirements, CMS is evaluating in this reconsideration only those criteria related to staff and other facility standards. Medicare payment for LVRS programs will continue to be limited to LVRS performed on beneficiaries that meet the patient clinical criteria outlined in our previous NCD.

The staff and facility requirements adopted by the Joint Commission appear to be directly derived from those originally developed by NHLBI to select facilities for the NETT trial.[6] These are the facility requirements that CMS had implicitly adopted in its previous decision on LVRS. The Joint Commission certification program standards thus appear to be commensurate with the facility standards previously recognized by CMS as being adequate to ensure LVRS would be delivered in a reasonable and necessary manner. In addition, we note that the program has an organized approach to performance improvement, measures patient health outcomes, and allows participants to be actively involved in making decisions about their care.

In sum, the standards that the Joint Commission is proposing to apply for certification of facilities furnishing LVRS services are consistent and equivalent with those CMS has found to be adequate to improve the health outcomes of Medicare beneficiaries. Adoption of the Joint Commission standards and methods will offer an opportunity for certification to any health care organization that shows the competence required to perform LVRS procedure successfully.

Not only do we believe that the Joint Commission standards are equivalent to the CMS standards, but we believe there are some significant additional benefits. The Joint Commission has incorporated specific performance measures and quality improvement requirements in its certification processes. The Joint Commission has also incorporated outcome measures among the applicable standards that will allow the facilities to meet the CMS data collection standard. In addition, the certification program has a mechanism for facility re-approval and the agency considers re-approval of LVRS facilities an unmet need.

For the reasons outlined above, CMS proposes to include Joint Commission certification as an alternative mechanism for facilities to become approved to perform Medicare covered LVRS. CMS reviewed the Joint Commission facility standards as printed in the October 25, 2004 Disease Specific Care Certification Program packet and we propose that coverage include facilities approved under these particular standards. Any changes in the facility standards in the Joint Commission accreditation program would need to be reevaluated by CMS. Any facilities certified under those altered standards would not be eligible for payment for LVRS performed on Medicare beneficiaries.

The LVRS facility standards and the proposed Joint Commission disease-specific certification process that we propose to incorporate into our national coverage determination are similar to but do not have the same legal effect as the standards and certification in 42 CFR Part 482 (Conditions of participation for hospitals). However, the options for certification as an LVRS facility identified in this NCD are considered necessary for LVRS to be reimbursed as reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act, but are not hospital conditions of participation.

In addition, as stated above, CMS will also consider future requests to reconsider this NCD from any other certifying entity that submits its criteria and methods and wishes to perform a comparable certification function as the Joint Commission.

Should facilities selected as NETT centers continue to be approved as LVRS facilities?

In the January 2004 decision, CMS included NETT centers as approved LVRS facilities in part because the centers were required to maintain a relationship with NHLBI which included notification of any changes in staffing related to LVRS. The formal relationship between the NETT centers and NHLBI ended in June 2004 when the last data for the NETT were collected. The trial has completely ended and the centers no longer maintain any formal relationship with NHLBI related to LVRS.

Since the formal relationship no longer exists, CMS can no longer be assured that the NETT centers are maintaining the standards that were once approved by NHLBI for participation in the clinical trial.

Accordingly, CMS proposes removing language in the NCD that was specifically included to provide coverage for patients enrolled in the NETT. This language is no longer applicable since the trial is not active and patients are no longer receiving services under the NETT protocol. Moreover, we propose that NETT facilities must meet one of the other criteria by 18 months following the effective date of this NCD to continue to receive Medicare payment for LVRS.

What impact will the proposed transplant regulation have on LVRS approved facilities[7]?

In the February 4, 2005, Federal Register, CMS proposed new criteria, called conditions of participation, for the approval and re-approval of Medicare lung and heart-lung transplant centers. When the regulation becomes final, CMS expects to rescind the current transplant NCDs. Thus, there may no longer be any transplant center criteria that would provide alternative facility standards that could be used to demonstrate that a facility is capable of performing LVRS in a reasonable and necessary manner. In that event, transplant facilities will need to become approved for LVRS under another available mechanism, such as that of the Joint Commission, in order to continue to be eligible to receive reimbursement for LVRS performed on Medicare beneficiaries.

Conclusion

Because the Joint Commission standards are at least equivalent to the current CMS LVRS facility standards, CMS proposes to recognize hospitals certified under the Joint Commission LVRS Disease Specific Care Program as appropriate facilities to perform LVRS.

CMS proposes to modify CMS publication 100-3 Section 240.1.A.2.c:

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Medicare provides coverage to those beneficiaries who are participating in the NETT trial for all services integral to the study and for which the Medicare statute does not prohibit coverage."

The NETT clinical trial has ended and, therefore, the language is no longer applicable.

Appendix A [PDF, 130KB]

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[1] National Emphysema Treatment Trial Research Group. A randomized trial comparing lung-volume-reduction surgery with medical therapy for severe emphysema. *NEJM.* May 22, 2003.

[2] Federal Register. 6140. Vol. 70. No. 23. February 4, 2005.

[3] NHLBI: Request for proposals for the National Emphysema Treatment Trial. *Commerce Business Daily.* June 3, 1996. The Executive Steering Committee (ESC) for the study assembled a panel of experts and reviewed all submitted RFPs in September 1996. Ultimately, 18 centers met the threshold requirements set out by the ESC.

[4] Joint Commission: Letter to CMS. March 31, 2004.

[5] Letter to CMS from the requestor. January 25, 2005.

[6] As mentioned above, the process utilized by Joint Commission to develop and review the LVRS-specific standards and elements of performance has been based on expert consensus and also open for review to a reasonably broad audience of health care organizations and individuals.

[7] Federal Register. 6140. Vol. 70. No. 23. February 4, 2005.

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